Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume XI Issue 1 January 2006

Patient Safety: A Laboratory Perspective

by Leonard Kargacin, DOH/LQA

Patient safety concerns have had a great deal of media attention in the last few years. All healthcare organizations are looking for ways to address problems that could lead to improved patient safety. Effective patient safety can only be achieved through a joint effort between all healthcare workers, the healthcare facility, and the patient.

The Washington State Hospital Association (WSHA) embarked on a program to seek ways to enhance its members' efforts on patient safety. In July 2004, the WSHA Board of Directors adopted the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Patient Safety Goals. WSHA has been working with its member hospitals toward achieving these goals and toward creating a culture of patient safety in their facilities.

The JCAHO patient safety goals adopted by the WSHA include:

- **Improve the accuracy of patient identification**
- **Improve the effectiveness of communication among caregivers**
- Improve the safety of using medications
- Improve the safety of using infusion pumps
- **Reduce the risk of healthcare-associated infections**
- Accurately and completely reconcile medications across the continuum of care
- Reduce the risk of patient harm resulting from falls

The list of goals contains some items that are outside of the purview of the clinical laboratory; however, the goals that are bolded in the list above directly apply. The discussion below provides guidance for enhancing the patient safety culture in the clinical laboratory in all facilities from physicians offices to the large reference laboratories. All government and private laboratory inspection agencies such as the Washington State Medical Test Site licensing program, the Centers for Medicare & Medicaid Services CLIA program, JCAHO, the College of American Pathologists (CAP), etc., have several questions in their laboratory inspection checklists pertaining to patient safety.

Improve the accuracy of patient identification

- Use at least two patient identifiers (neither should be the patient's location) whenever collecting laboratory samples or administering medications or blood products.

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Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

Patient Safety, continued from page 1

- Use two identifiers to label sample collection containers in the presence of the patient.
- Establish procedures to maintain sample identity throughout the pre-analytical, analytical, and post-analytical processes, including any aliquots and dilutions made of the patient sample.

Improve the effectiveness of communication among caregivers

- For verbal or telephone orders or for telephonic reporting of critical tests results, verify the complete order or test result by having the person receiving the order or test results "read-back" the complete order or test results. NOTE: For example, the laboratory should give all test results to the receiver. Once the complete report has been given, the laboratory asks that the receiver "read-back" the entire report. This is the only effective mechanism that ensures that all of the laboratory results were taken down correctly by the receiver.
- Standardize the list of abbreviations, acronyms, and symbols that are acceptable in the facility.
- Take action to improve the timeliness of reporting in general.

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http://www.doh.wa.gov/EHSPHL/PHL/default.htm

- Take action to improve the timeliness of receipt by the responsible licensed caregiver of critical test results and values.
- Report all values defined as critical by the laboratory to a responsible licensed caregiver within time frames established by the laboratory. When the patient's responsible licensed caregiver is not available, ensure that there is a mechanism in place to report the critical information to an alternative responsible caregiver.

Reduce the risk of healthcare-associated infections

- Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines (http://www.cdc.gov/handhygiene/).

In addition, the following quality assurance (QA) activities performed by the laboratory ultimately result in improved patient safety:

- Document initial personnel training and yearly competency checks.
- Follow written procedures and policies.
- Do on-going performance and review of external quality control and proficiency testing.
- Define specimen acceptance and rejection policies.
- Assess problems and discuss them with staff.
- Document actions taken to identify and correct problems or potential problems.
- Issue corrected reports when indicated.
- Respond to patient complaints and concerns.

Websites of interest with patient safety information or links:

Washington State Hospital Association
http://www.wsha.org
JCAHO
http://www.jcaho.org/
National Patient Safety Foundation
http://www.npsf.org/
Washington Patient Safety Coalition
http://www.wapatientsafety.org/
Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/
Washington State Medical Association
http://www.wsma.org/
College of American Pathologists (CAP)
http://www.cap.org/apps/cap.portal
COLA
http://www.cola.org/

Good Laboratory Practices for Waived Tests

The Centers for Disease Control and Prevention (CDC) recently published a guidance document titled "Good Laboratory Practices for Waived Testing Sites." This document was in the November 11, 2005, edition of the *Morbidity & Mortality Weekly Report* published by CDC.

The document represents the findings from on-site inspections of CLIA-waived laboratories conducted by the Centers for Medicare & Medicaid Services CLIA Program survey staff and by CDC throughout the country from 1999-2004. Data obtained through the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network questionnaires appear prominently throughout the document. The major problem identified in these studies and surveys was not following the manufacturer's instructions especially with regard to quality control. The guidance document includes an overview of crucial steps that must be considered throughout all phases of the testing process before introducing waived testing or offering a new waived test. The information found in the manufacturer's package insert is highlighted so that people are aware of what information can be found in the package insert and why this information is important.

Any medical test site performing waived testing would benefit from a review of these recommendations for good laboratory practices. The report can be accessed online at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm.

Laboratory-Based Practice Guidelines

A critical area of concern in the current cost-conscious health care environment is optimization of service delivery. Over-utilization of laboratory testing can lead to needless and costly treatment for the patient. Under-utilization can result in a misdiagnosis and delays in treatment. To address inappropriate or unnecessary use of laboratory testing services, the Clinical Laboratory Advisory Council decided to establish a process for developing practice guidelines for clinical laboratory testing. The guidelines are for educational purposes only.

The intent of the guidelines is to help laboratorians answer questions they may get from clinicians on appropriate test ordering. The guidelines will also be useful to clinicians as a review of a typical test-ordering pattern for asymptomatic patients. The guidelines are a compilation of existing data, not original work by the Council. For the format, the Council elected to summarize existing information into simple, easy-to-use flow charts. Once a test has been identified by the Council as a candidate for a guideline, a Council workgroup is formed to develop a proposed guideline. The draft guideline is reviewed by the entire Council, members of the state's laboratory community and appropriate medical professional societies. Comments from the reviewers are evaluated by the Council workgroup and incorporated into the final document. The finalized guideline is disseminated to all clinical laboratories and other interested parties through this newsletter.

FOR EDUCATIONAL PURPOSES ONLY!

The guidelines should be used strictly as guidelines. The individual clinician is in the best position to determine which tests are most appropriate for a particular patient

Guidelines developed by the Council that have been previously published in E**LAB**ORATIONS are listed in the box on page 1 of this newsletter. This issue of E**LAB**ORATIONS contains the Group B Streptococcus guideline

Procedures for collecting and processing clinical specimens for group B streptococcal culture and performing susceptibility testing to clindamycin and erythromycin

Procedures for collecting clinical specimens for culture of group B streptococcus at 35 - 37 weeks' gestation

- Swab the lower vagina (vaginal introitus), followed by the rectum (i.e., insert swab through the anal sphincter) using the same swab or two different swabs. Cultures should be collected in the outpatient setting by the healthcare provider or the patient herself, with appropriate instruction. Cervical cultures are not recommended and a speculum should not be used for culture collection.
- Place the swab(s) into a nonnutritive transport medium. Appropriate transport systems (e.g., Amies or Stuart's without charcoal) are commercially available. If vaginal and rectal swabs were collected separately, both swabs can be placed into the same container of medium. Transport media will maintain GBS viability for up to 4 days at room temperature or under refrigeration.
- Specimen labels should clearly identify that specimens are for group B streptococcal culture. If susceptibility testing is ordered for penicillin-allergic women, specimen labels should also identify the patient as penicillin-allergic and should specify that susceptibility testing for clindamycin and erythromycin should be performed if GBS is isolated.

Procedures for processing clinical specimens for culture of group B streptococcus

- Remove swab(s) from transport medium.[2] Inoculate swab(s) into a recommended selective broth medium, such as Todd-Hewitt broth supplemented with either gentamicin (8 ug/ml) and nalidixic acid (15 ug/ml), or with colistin (10 ug/ml) and nalidixic acid (15 ug/ml). Examples of appropriate commercially available options include Trans-Vag broth supplemented with 5% defibrinated sheep blood or LIM broth.[3]
- Incubate inoculated selective broth for 18-24 hours at 35-37° C in ambient air or 5% CO_2. Subculture the broth to a sheep blood agar plate (e.g., tryptic soy agar with 5% defibrinated sheep blood).
- Inspect and identify organisms suggestive of GBS (i.e., narrow zone of beta hemolysis, gram-positive cocci, catalase negative). Note that hemolysis may be difficult to observe, so typical colonies without hemolysis should also be further tested. If GBS is not identified after incubation for 18-24 hours, reincubate and inspect at 48 hours to identify suspected organisms.
- Various streptococcus grouping latex agglutination tests or other tests for GBS antigen detection (e.g., genetic probe) may be used for specific identification, or the CAMP test may be employed for presumptive identification.

Procedures for clindamycin and erythromycin disk susceptibility testing of isolates, when ordered for penicillin-allergic patients [4]

- Use a cotton swab to make a suspension from 18-24 hour growth of the organism in saline or Mueller-Hinton broth to match a 0.5 McFarland turbidity standard.
- Within 15 minutes of adjusting the turbidity, dip a sterile cotton swab into the adjusted suspension. The swab should be rotated several times and pressed firmly on the inside wall of the tube above the fluid level. Use the swab to inoculate the entire surface of a Mueller-Hinton sheep blood agar plate. After the plate is dry, use sterile forceps to place a clindamycin (2 ug) disk onto half of the plate and an erythromycin (15 ug) disk onto the other half).
- Incubate at 35°C in 5% CO_2 for 20-24 hours.
- Measure the diameter of the zone of inhibition using a ruler or calipers. Interpret according to NCCLS guidelines for *Streptococcus* species other than *S. pneumoniae* (2002 breakpoints:[4] clindamycin: $\geq$19 mm = susceptible, 16-18 = intermediate, $\leq$15 = resistant; erythromycin: $\geq$21 mm = susceptible, 16-20 = intermediate, $\leq$15 = resistant).

[2] Before inoculation step, some laboratories may choose to roll swab(s) on a single sheep blood agar plate or CNA sheep blood agar plate. This should be done only in addition to, and not instead of, inoculation into selective broth. The plate should be streaked for isolation, incubated at 35-37°C in ambient air or 5% CO_2 for 18-24 hours and inspected for organisms suggestive of GBS as described above. If suspected colonies are confirmed as GBS, the broth can be discarded, thus shortening the time to obtain culture results.

[3] Source: Fenton, LJ, Harper MH. Evaluation of colistin and nalidixic acid in Todd-Hewitt broth for selective isolation of group B streptococci. J Clin Microbiol 1979;9:167-9. Although Trans-Vag medium is often available without sheep blood, direct comparison of medium with and without sheep blood has shown higher yield when blood is added. LIM broth may also benefit from the addition of sheep blood, although the improvement in yield is smaller and sufficient data are not yet available to support a recommendation.

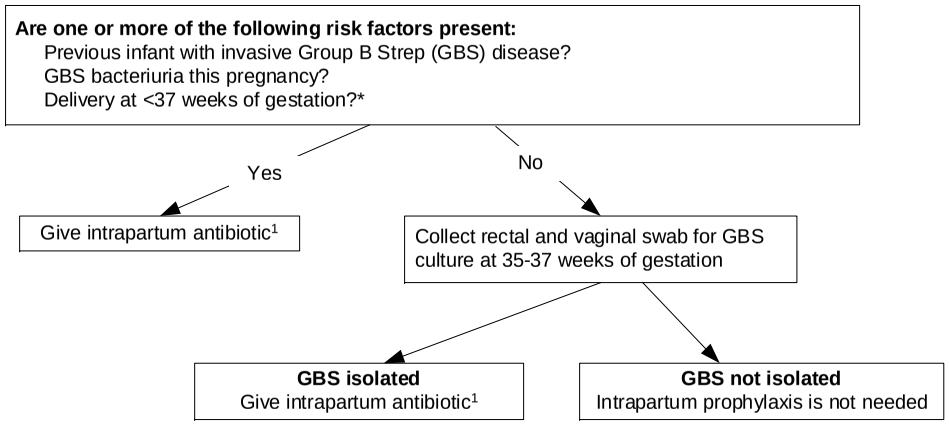
[4] Source: NCCLS. Performance standard for antimicrobial susceptibility testing, M100-S12, Table 2H, Wayne, Pa: NCCLS, 2004. NCCLS recommends disk diffusion (M-2) or broth microdilution testing (M-7) for susceptibility testing of GBS. Commercial systems that have been cleared or approved for testing of streptococci other than *S. pneumoniae* may also be used. Penicillin susceptibility testing is not routinely recommended for GBS because penicillin-resistant isolates have not been confirmed to date.

Group B Streptococcus Guidelines

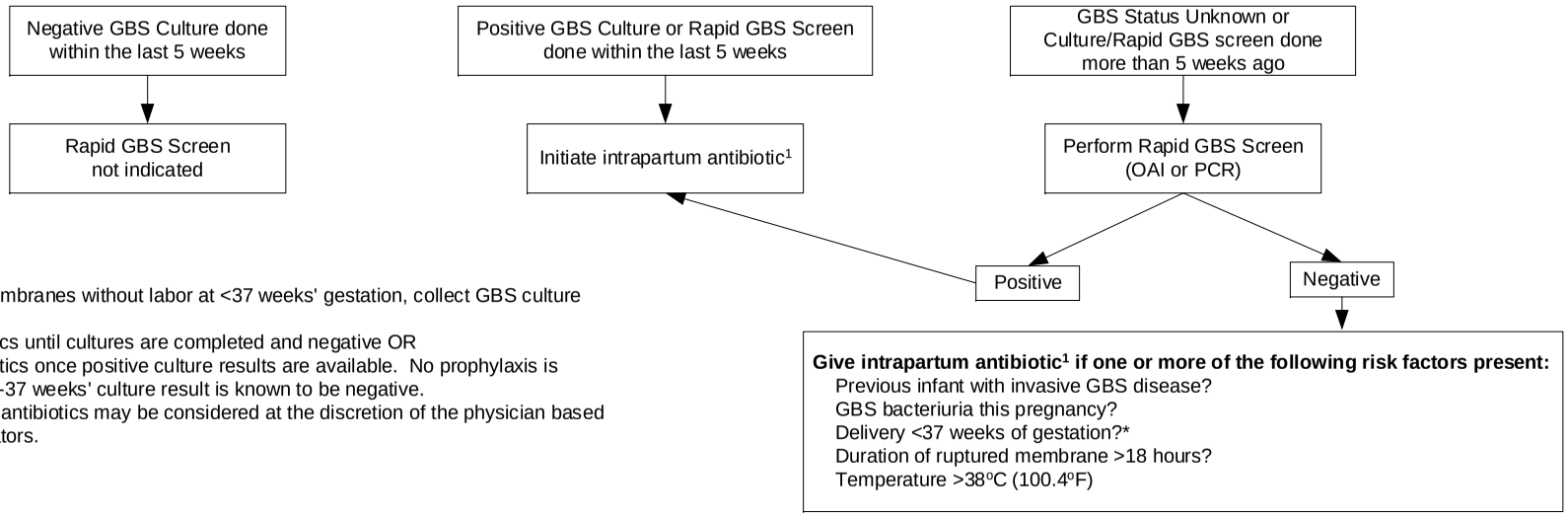
Washington State Clinical Laboratory Advisory Council
November 2005

FOR EDUCATIONAL PURPOSES ONLY
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Prevention Strategy for Early Onset Using Prenatal Screening at 35 - 37 Weeks' Gestation:



At the Time of Delivery



* For ruptured membranes without labor at <37 weeks' gestation, collect GBS culture and either:
a) Give antibiotics until cultures are completed and negative OR
b) Begin antibiotics once positive culture results are available. No prophylaxis is needed if 35-37 weeks' culture result is known to be negative.

[1] Broad spectrum antibiotics may be considered at the discretion of the physician based on clinical indicators.

References:
1) Prevention of Perinatal Group B Streptococcal Disease. Centers for Disease Control and Prevention. MMWR 2002:51(RR11); 1-22.
2) Screening and Management Protocols for Group B Streptococcus in Pregnancy. Cary, J.C. Current Women's Health Reports 2002, 4:238-244.
3) Reisner D.P., et al. (2000). Performance of a group B streptococcal prophylaxis protocol combining high-risk factors and low-risk screen. Am J Obstet Gynecol, 182(6), pp 1335-43.

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The report can be accessed online at:
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/EHSPHL/PHL/train.htm)

Basic Microscopy
February 8 Shoreline

Basic Blood Cell Morphology
March 8 OR 9 Shoreline

Packaging & Shipping of Infectious Substances
March 24 Shoreline

WSSCLS/NWSSAMT Spring Meeting
April 20-22, 2006 Seattle

Northwest Medical Laboratory Symposium
October 18-21, 2006 Portland

13th Annual Clinical Laboratory Conference
November 2006 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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